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EPAR summary for the public

Forxiga

dapagliflozin

This is a summary of the European public assessment report (EPAR) for Forxiga. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Forxiga.

What is Forxiga?

Forxiga is a medicine that contains the active substance dapagliflozin. It is available as tablets (5 and 10 mg).

What is Forxiga used for?

Forxiga is used to treat adults with type 2 diabetes.

Forxiga can be used on its own in patients whose blood glucose (sugar) levels are not satisfactorily controlled on diet and exercise alone and who cannot tolerate metformin (another antidiabetes medicine).

Forxiga can also be used as an 'add-on' to other antidiabetes medicines, including insulin, when these medicines together with exercise and diet are not providing adequate control of the diabetes.

The medicine can only be obtained with a prescription.

How is Forxiga used?

The recommended dose of Forxiga is 10 mg once a day. If Forxiga is used in combination with insulin or medicines that make the body produce insulin, their doses may need to be reduced to decrease the risk of hypoglycaemia (low blood sugar levels). As the effects of Forxiga are dependent on kidney function, the effectiveness of the medicine is reduced in patients with reduced kidney function. Therefore, the use of Forxiga is not recommended in patients with moderately or severely reduced

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kidney function. For patients with severely reduced liver function a starting dose of 5 mg is recommended.

How does Forxiga work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. This leads to high levels of glucose in the blood.

The active substance in Forxiga, dapagliflozin, works by blocking a protein in the kidneys called sodium-glucose co-transporter 2 (SGLT2). SGLT2 is a protein that absorbs glucose from the urine into the bloodstream as the blood is filtered in the kidneys. By blocking the action of SGLT2, Forxiga causes more glucose to be removed via the urine, thereby reducing the levels of glucose in the blood.

How has Forxiga been studied?

The effects of Forxiga were first tested in experimental models before being studied in humans.

Forxiga on its own has been compared with placebo (a dummy treatment) in two studies in 840 patients. A third study compared Forxiga with a sulphonylurea (glipizide), both taken in combination with metformin in 814 patients. Four other studies compared Forxiga with placebo, when used as an add-on to either metformin, a sulphonylurea (glimepiride), a thiazolidinedione or insulin in 2,370 patients.

In all of the studies, the main measure of effectiveness was the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Forxiga shown during the studies?

Forxiga was more effective than placebo at reducing the levels of HbA1c when used alone and in combination with other antidiabetes medicines. When Forxiga was used on its own at a dose of 10 mg, it decreased HbA1c levels by 0.66% more than placebo after 24 weeks. When Forxiga was added to other antidiabetes medicines, Forxiga 10 mg decreased HbA1c levels by 0.54-0.68% more than placebo after 24 weeks.

When compared with a sulphonylurea, Forxiga was at least as effective and both medicines reduced HbA1c levels by 0.52% after 52 weeks.

What is the risk associated with Forxiga?

The most common side effect with Forxiga (seen in more than 1 patient in 10) is hypoglycaemia when used with a sulphonylurea or insulin. For the full list of side effects reported with Forxiga, see the package leaflet.

Forxiga must not be used in people who are hypersensitive (allergic) to dapagliflozin or any of the other ingredients.

Why has Forxiga been approved?

The CHMP concluded that Forxiga was shown to be effective in lowering blood glucose levels in patients with type 2 diabetes, when given alone or in combination with other antidiabetes medicines with

different mechanisms of actions. In addition, beneficial reductions in weight and blood pressure were seen in patients treated with Forxiga.

Commonly seen side effects were related to the way the medicine works, such as increased genital and, to a smaller degree, urinary tract infection (infection of the structures that carry urine), and are considered to be manageable. A small but higher number of bladder, breast and prostate cancer cases were seen in patients who took Forxiga compared with patients who took placebo. However, there was no difference between the groups when cancer overall was considered and preclinical studies investigating the risk of developing cancer with Forxiga did not show this risk. The Committee has recommended that further studies be carried out to investigate this concern. The CHMP concluded that the benefits of Forxiga outweigh its risks and recommended that it be granted marketing authorisation.

Other information about Forxiga

The European Commission granted a marketing authorisation valid throughout the European Union for Forxiga on 12 November 2012.

The full EPAR for Forxiga can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Forxiga, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2012.